

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application No.:	10/068,812	Confirmation No.:	8436
Applicant :	Richard J. Greff		
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TC/A.U. :	1611		
Examiner :	Ghali, Isis A.D.		
Title :	CROSS-LINKED GELATIN COMPOSITION COMPRISING A WETTING AGENT		
Docket No. :	1001.2216102		
Customer No. :	11050		

REPLY BRIEF

Mail Stop Appeal Brief - Patents
Assistant Commissioner for Patents
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By _____

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Dear Sirs:

Pursuant to 37 C.F.R. § 41.41, Appellant hereby submits this Reply Brief in furtherance of the Notice of Appeal filed on October 7, 2010, the Notice of Panel Decision from Pre-Appeal Review dated mailed November 5, 2010, the Appeal Brief filed on December 7, 2010, and the Examiner's Answer mailed February 2, 2011. Appellant authorizes the fee prescribed by 37 C.F.R. § 41.20(b)(2) in the amount of \$540 to be charged to Deposit Account No. 50-0413. Permission is hereby granted to charge or credit Deposit Account No. 50-0413 for any errors in fee calculation.

ARGUMENT

Appellant acknowledges the withdrawal of the 35 U.S.C. §112, first paragraph rejections.

As an initial matter, the Examiner's Answer repeats the earlier error of equating an article containing a wetting agent dispersed uniformly therein with an article which includes surfaces coated with a wetting agent. This distinction has been discussed more fully in the Appeal Brief. As illustrated at the top of page 9 of the brief, there is a clear structural difference between the two articles. This structural difference encompasses a coating on the surfaces of the sponge as a whole and/or on structures within the sponge such as struts and/or walls forming the foam. There is no indication in the disclosure of Pawelchak that a post applied surface coating is structurally or functionally equivalent to that material dispersed within a sponge and it would not be understood to be equivalent by one of ordinary skill in the art.

It is believed that wetting agent which is dispersed within the material of the sponge, as opposed to present as a coating deposited on substantially all of the internal and external surfaces thereof, is relatively ineffective in promoting rapid wetting and hydration of the material of the sponge for the reason that the majority of such dispersed wetting agent has no contact with the body fluids until the material of the sponge is already significantly hydrated by which time the potential benefit is greatly reduced. Release of a wetting agent after hydration is largely complete is not expected to be as effective for decreasing hydration time of the sponge as positioning the wetting agent on the surfaces of the sponge where it may be almost entirely dissolved in the body fluids, producing a high local concentration, and may promote wetting much earlier in the hydration process.

As discussed in detail in the Appeal Brief, Pawelchak does not teach or otherwise suggest coating the surfaces of the foam with a wetting agent as recited in the pending claims. The only material identified by the Examiner as a wetting agent, appears to be a surface tension modifier, identified as one of a group of surfactants exemplified by Tween 60, which are said to "stabilize the gas suspension and enhance the quality of the foam" at col. 4, lines 47-52, are added to the sponge only as components of an aqueous dispersion which is subsequently foamed. The Examiner repeatedly errs in equating a

foam, which is subjected to further processing including lyophilization and optional cross-linking, to the “preformed cross-linked gelatin sponge” of the claims.

The teaching of Pawelchak is that Tween 60, if present, is present prior to foaming and consequently prior to “forming” or cross-linking and thus does not disclose a pre-formed cross-linked gelatin sponge to which a coating is applied. A preformed aqueous foam of Pawelchak is not equivalent to a sponge, much less a crosslinked sponge. Given the teaching of Pawelchak, the addition of Tween 60 as a coating on the formed and cross-linked sponge would serve no disclosed purpose. There is no need to stabilize a foam which has already been cross-linked to stabilize the structure.

Tween 60 appears only once in the disclosure of Pawelchak in the list of foam stabilizers as mentioned above.

Those portions of Pawelchak which appear to disclose the structure of the foams in question are found primarily in the Examples beginning near the top of column 6. Those examples have been analyzed in detail in the Appeal Brief. Summarizing, Examples 1-20 do not include a surface tension modifier and are not cross-linked. Example 21 is cross-linked after foaming without the addition of a surface tension modifier before or after freezing or lyophilizing. Example 22 refers to the composition of Example 1 and does not include an identified surface tension modifier or cross-linking. Example 23 compares a commercial product to that of Example 1 and does thus not disclose a surface tension modifier or cross-linking. The Examiner correctly notes that Appellant agrees that the sponges of Pawelchak may be cross-linked; however Appellant emphatically does not agree that the sponges of Pawelchak necessarily are cross-linked or that the surfaces of the cross-linked sponge disclosed are, at any time, substantially coated with a coating of wetting agent.

Accordingly, Pawelchak does not disclose coating the surfaces of a preformed cross-linked sponge with a wetting agent. The disclosure of Pawelchak appears to be limited to the possible inclusion of a surface tension modifier in an aqueous precursor to a foam which may optionally be cross-linked later.

Contrary to the Examiner’s position, the biocompatible, hemostatic, cross-linked gelatin composition of the claims is structurally differentiated from Pawelchak by the presence of the wetting agent as a coating on the surfaces of a cross-linked gelatin sponge

as opposed to dispersed within the hydrocolloids, gelatin, pectin and sodium carboxymethyl cellulose of Pawelchak.

The combination of coating a cross-linked sponge and the utilization of a coating solution comprising the wetting agent and a non-aqueous solvent tends to ensure that the material of the sponge does not significantly swell during the soaking period and thus that the wetting agent does not significantly enter the cross-linked gelatin as well as ensuring that the coating solution does not significantly promote collapse of the sponge by hydrating it. It is the presence of the wetting agent as a coating on a substantial portion of the surface of the sponge rather than within the material of the sponge which imparts patentability to the claimed invention. The claims, while listing compositional elements, are not compositional, *per se*, and do include structural limitations in that the wetting agent is present as a coating on a substantial portion of the internal and external surfaces of the sponge.

The Examiner repeats the earlier error of characterizing the non-aqueous solvent of the claims as “the aqueous solvent” at page 8. Any aqueous composition, such as that employed by Pawelchak in the creation of the sponge is removed before the wetting agent coating is applied from a non-aqueous solvent.

As noted by the Examiner’s Answer, the coated structure of the pending claims suffices to differentiate it from the product of Pawelchak and the unobvious difference is also recited in the claims as “wherein the wetting agent decreases hydration time of the gelatin sponge”. The final clause of claim 22 was unnecessarily introduced in an effort to advance prosecution in the face of the Examiner’s erroneous insistence that an object having a surface coating is identical to an object having the material of the coating dispersed therein. There is no indication in the disclosure of Pawelchak that the presence or absence of a dispersed foam stabilizing surface tension modifier has any effect on hydration times and the structure anticipated to result from the dispersion of any optional surfactant within the bulk of the material from which the sponge is formed would be expected to delay the functional availability of the foam stabilizer within the bodily fluid permeating the sponge until hydration and the resulting swelling are substantially complete.

The Examiner's discussion beginning near the bottom of page 10 of the Examiner's Answer both acknowledges that "Pawelchak does not disclose a wetting agent coating on at least a substantial portion of the surface of a preformed cross-linked gelatin sponge" (emphasis added), and insists to the contrary that the disclosure of Pawelchak "would inevitably leave some of the wetting agent along with other ingredients on the surface of the article after drying". Appellant notes that Pawelchak does not inherently disclose that a surface tension modifier is present and thus would not necessarily or "inevitably" leave a component which is not present on the surface of the article. Further, the Examiner has not presented a reasoned and rational argument why one of skill in the art would expect any optional dispersed surface tension modifier present to partition such that it would remain on the surface of the sponge composition rather than seeking a preferred environment within the material of the sponge. The polysorbates are oily liquids which would reasonably be expected to be relatively hydrophobic and thus would tend to partition away from the aqueous phase adjacent to the material of the sponge and to prefer the interior of the sponge material. The mere initial formation of a mixture does not in general dictate the composition of an exposed surface resulting from further processing of the mixture.

Further still, the Examiner makes the puzzling statement: "The claims do not require coating, rather coating of substantial portion". [sic] Appellant asserts that the claims do require coating as recited, for example, in the phrase "the wetting agent is coated on ... the surface" and the claims further recite that the coating is "coated on at least a substantial portion of the surface of the preformed gelatin sponge". As noted above the disclosure of Pawelchak does not disclose that a wetting agent is necessarily present and thus does not inherently disclose the remaining elements and relationships of the pending claims. Similarly, Pawelchak does not inherently disclose that the resulting sponge is cross-linked.

The coated structure recited in the claims is not disclosed in Pawelchak in as great detail as contained in the claims and the elements, wetting agent coating and preformed cross-linked gelatin composition, if present, are not arranged as recited in the claims. In the absence of the recited structure, Pawelchak cannot disclose the decreased hydration time associated with the structure.

As discussed in the Appeal Brief, Appellant has presented experimental evidence that the wetting agent surface coating significantly reduces hydration times. As further discussed in the Appeal Brief, the incorporation of Tween 60 into the foaming composition of Table 5, line 5 results in premature collapse of the foam, and thus one of ordinary skill in the art would not view a collapsed foam produced with Tween 60 dispersed therein as equivalent in performance to a foam to which Tween 60 had been added as a coating to stabilized, cross-linked foam of the invention. Pawelchak does not disclose a foam stabilized by Tween 60 or other surface tension modifier and thus the influence of such dispersed agents on hydration times, if any, is not disclosed.

The Examiner asserts that Tween 60 is not recited in claim 22, which is correct; however Tween 60 is believed to be the only foam stabilizer which the Examiner has relied upon in presenting the arguments to date and its performance, or rather the lack thereof in the manner asserted by the Examiner is believed to be pertinent to the Examiner's further assertions regarding the "inherent" behavior of the compositions disclosed by Pawelchak. The Examiner erroneously asserts that the weight of whole blood or body exudate which the material of Pawelchak eventually is capable of absorbing and holding is somehow related to the hydrations times required to absorb those weights of blood or exudate. As discussed previously, Pawelchak does not disclose preformed cross-linked gelatin sponges which exhibit decreased hydration times as a result of the presence of a wetting agent coating on the surfaces of the sponge. Indeed, Pawelchak does not expressly or inherently describe cross-linked preformed sponges which include a foam stabilizing surfactant.

The Examiner repeats earlier errors in asserting that the presence of optional elements supplied at times incompatible with the formation of the claimed sponge structure "is evident [*sic*] of their being essential elements in preferred embodiments", yet they do not appear together in the exemplified embodiments and several of the examples do not contain either surfactant or cross-linking. The Examiner continues the erroneous analysis by asserting that hydration times, undisclosed by Pawelchak, are inherent for the reason that all of the optional components are present in the disclosed embodiments while ignoring the differences in structure which alter the availability and concentrations of the materials and thus their ability to affect hydration times. There is no indication within the

disclosure of Pawelchak that a post-applied surface coating is structurally or functionally equivalent to a material uniformly dispersed within the material of a sponge and it would not be understood to be equivalent by one of ordinary skill in the art. As noted above, Appellant has provided experimental evidence in the application that Tween 60, far from decreasing hydration times, results in the collapse of a precursor gelatin foam which prevented further testing.

Rejections of claims 26 and 31 rely upon independent claim 22 being nonobvious in view of Pawelchak and have been discussed in greater detail in the Appeal Brief.

CONCLUSION

For the reasons stated above and in the Appeal Brief, claims 22-33 and 42 are not anticipated by Pawelchak or obvious over Pawelchak in view of Yasushi or Song and the Examiner's rejections of those claims under 35 U.S.C § 102 and § 103 should be overruled.

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Respectfully submitted,


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